



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

JUL 14 2014

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL #7009 1680 0000 7667 0999
RETURN RECEIPT REQUESTED

Mr. Steven Coventry
Vice President
Akorn, Inc.
1222 W. Grand Avenue
Decatur, Illinois 62522

Re: Notice of Violation
RCRA Compliance Evaluation Inspection – Akorn, Inc.
EPA ID No.: ILD 984 906 412

Dear Mr. Coventry:

On April 16, 2014 a representative of the U.S. Environmental Protection Agency inspected the Akorn, Inc. (Akorn) facility, located in Decatur, Illinois. The purpose of that inspection was to evaluate Akorn's compliance with certain provisions of the Resource Conservation and Recovery Act (RCRA); specifically, those regulations related to the generation, treatment and storage of hazardous waste. A copy of the inspection report is enclosed for your reference.

Based on information provided by Akorn personnel, a review of records and the inspector's personal observations while inspecting the facility, EPA has determined that Akorn is engaged in the storage of hazardous waste without a hazardous waste storage permit, and is in violation of certain requirements of the Illinois Administrative Code (IAC) and the U.S. Code of Federal Regulations (CFR). To be eligible for the exemption from the requirement to obtain a hazardous waste storage permit, Akorn, as a large quantity generator, must be in compliance with the conditions of 35 IAC § 722.134 (a) and (c) [40 CFR § 262.34(a) and (c)]. We find that Akorn was not in compliance with the following conditions and requirements of RCRA and, therefore, was not exempt from having a hazardous waste storage permit:

1. In order to avoid the need for a hazardous waste storage permit, a large quantity generator of hazardous waste may accumulate as much as 55-gallons of hazardous waste or one quart of acutely hazardous waste in containers at or near the point of generation which is under the control of an operator of the process generating the waste, provided that the containers are marked with either the words, "Hazardous Waste," or with other words that identify the contents. See 35 IAC 722.134(c)(1)(B) [40 CFR 262.34(c)(1)(ii)].

At the time of the April 16, 2014 inspection, 4-liter satellite accumulation containers of HPLC hazardous waste solvent in the QC/RD lab were not marked with either the words "Hazardous Waste" or with other words that identify the contents. Akorn, therefore, failed to comply with the conditions for a hazardous waste storage permit exemption, and violated the hazardous waste container marking and identification requirement.

2. In order to avoid the need for a hazardous waste storage permit, a large quantity generator of hazardous waste using containers to accumulate hazardous waste must clearly mark the date upon which each period of accumulation begins. See, 35 IAC § 722.134(a)(2) [40 CFR § 262.34(a)(2)].

At the time of the April 16, 2014 inspection, twenty-two 4-liter containers of HPLC hazardous waste solvent were not marked with the date upon which each period of accumulation begins. Akorn, therefore, failed to comply with the conditions for a hazardous waste permit exemption, and violated the hazardous waste container accumulation date marking requirement.

3. In order to avoid the need for a hazardous waste storage permit, a large quantity generator of hazardous waste using containers to accumulate hazardous waste must label or mark clearly each container with the words "Hazardous Waste." See, 35 IAC § 722.134(a)(3) [40 CFR § 262.34(a)(3)].

At the time of the April 16, 2014 inspection, twenty-two 4-liter containers of HPLC hazardous waste solvent were not labeled or marked with the words "Hazardous Waste." Akorn, therefore, failed to comply with the conditions for a hazardous waste storage permit exemption, and violated the hazardous waste container marking and identification requirement.

4. In order to avoid the need for a hazardous waste storage permit, a large quantity generator must maintain records that document that the required training had been given to, and completed, by facility personnel. See, 35 IAC §§ 722.134(a)(4) and 725.116(d)(4) [40 CFR §§ 262.34(a)(4) and 265.16(d)(4)]. This is also a requirement of owners and operators of hazardous waste storage facilities under 35 IAC 724.116 (d)(4) [40 CFR 264.16 (d)(4)].

At the time of the April 16, 2014 inspection, Akorn was unable to provide documentation showing that employees took hazardous waste emergency response refresher training in the years 2011 and 2012. Akorn, therefore, failed to comply with the conditions for a hazardous waste storage permit exemption, and violated the training recordkeeping requirement.

5. In order to avoid the need for a hazardous waste storage permit, a large quantity generator's written contingency plan must include, among other things, the names,

addresses, and phone numbers (office and home) of all persons qualified to act as the emergency coordinator. See, 35 IAC §§ 722.134(a)(4) and 725.152(d) [40 CFR §§ 262.34(a)(4) and 265.52(d)]. This is also a requirement of owners and operators of hazardous waste storage facilities under 35 IAC § 724.152 [40 CFR § 264.52(d)].

At the time of the April 16, 2014 inspection, Akorn's contingency plan did not list the name, address, and phone number (office and home) of the current primary and alternate emergency coordinators. Akorn, therefore, failed to comply with the above-mentioned condition for a permit exemption and violated the above-referenced contingency plan requirements.

6. A small quantity handler of universal waste must label or mark clearly each waste battery or tank in which batteries are contained with any of the following words, "Universal Waste-Batteries," or "Waste Batteries," or "Used Batteries." See 35 IAC § 733.134(a) [40 CFR § 273.34(a)].

At the time of the April 16, 2014 inspection, the EPA inspector observed two containers of waste batteries that were not marked with any of the above phrases. Akorn, therefore, violated the universal waste marking requirement.

7. A small quantity handler of universal waste must manage used lamps in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions. See 35 IAC § 733.113(d)(1) [40 CFR § 273.13(d)(1)].

At the time of the April 16, 2014, inspection, Akorn was storing open containers of loose waste lamps in the north boiler room. Akorn, therefore, violated the universal waste lamp storage requirement.

8. A small quantity handler of universal waste must label or mark each lamp or container or package in which such lamps are contained with one of the following phrases: "Universal Waste Lamps," "Waste Lamps," or "Used Lamps." See, 35 IAC § 733.114(e) [40 CFR § 273.14(e)].

At the time of the April 16, 2014, inspection, Akorn was storing open containers of waste lamps without any of the above phrases. Akorn, therefore, violated the universal waste marking requirement.

9. A large quantity generator that accumulates hazardous waste on-site and does not meet the conditions for a permit exemption of 35 IAC § 722.134 [40 CFR § 262.34] is an operator of a hazardous waste storage facility and is required to obtain a hazardous waste storage permit. See, 35 IAC §§ 703.121(c) and 702.123 [40 CFR §§ 270.1(c) and 270.13].

Upon failing to meet the conditions identified in items 1 through 5 above, Akorn's failure to apply for and obtain a hazardous waste storage permit violated the permitting requirements of 35 IAC §§ 703.121(c) and 702.123 [40 CFR §§ 270.1(c) and 270.13].

At this time, EPA is not requiring Akorn to submit an application for a hazardous waste storage permit so long as it immediately establishes and maintains compliance with the conditions for a permit exemption specified in 35 IAC 722.134 [40 CFR § 262.34].

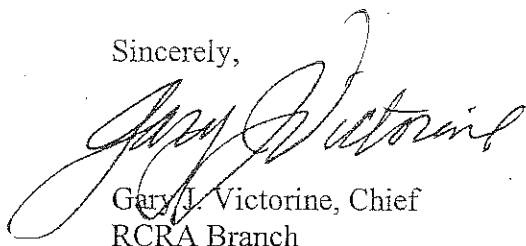
According to Section 3008(a) of the RCRA, EPA may issue an order assessing a civil penalty for any past or current violation requiring compliance immediately or within a specified time period. Although this letter is not such an order, you are hereby requested to submit a response in writing to this office no later than thirty (30) days after receipt of this letter documenting the actions, if any, which have been taken since the inspection to establish compliance with the conditions and requirements listed above.

You should submit your response to:

Sheila Burrus
Environmental Protection Specialist
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd (LR-8J)
Chicago, Illinois 60604

If you have any questions regarding this letter, please contact Ms. Burrus, of my staff, at (312) 886-3587.

Sincerely,



Gary L. Victorine, Chief
RCRA Branch

Enclosure

cc: Todd Marvel, (todd.marvel@illinois.gov)